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EXAMINER

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

Receipt of Amendments/Remarks filed 3-5-09 is acknowledged. Claims 1-20, 22, and 30-32 stand cancelled. New claims 38-40 are added. Claims 21, 23-29, 33-40 are pending.

Response to Arguments

1. Applicant's arguments filed 3-5-09 have been fully considered but they are not persuasive.
2. Applicants' argue that the entire prior art cited removes skin and does not teach not removing stratum corneum or leaving epidermis intact. However, the following paragraphs provide evidence that instant invention does involve removing epidermis and also stratum corneum (previously applied rejections reinstated) and therefore the argument that the cosmetic benefit attained when Applicant's exploding carbon particle method (which does not remove the skin) is combined with topical retinoic acid is not persuasive.

The following is a reinstatement of the rejection made previously in view of the amendment to claim 21 that the exploding a contaminant on the skin leaves epidermis intact and undamaged and in claims 38 and 40 that does not remove stratum corneum.

Claim Rejections - 35 USC § 112

Claims 21, 23-29, 33-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Instant claims **21, 23-29, 33-40** are recite epidermis is intact and that the stratum corneum is not removed. The *originally* filed specification disclosed, "The energy from the laser is adjusted to be just sufficient to cause the particles to explode. As the particles explode, they cause the removal of the stratum corneum and the mineral oil 20 penetrates into the epidermis producing hydration of the epidermis by retarding the evaporation of water (see Fig. 2)." This is also present in instant amended specification (see amendment of 3-5-09).

First, page 5 of the specification is noted in which applicant discloses, "The Tankovich processes disclosed in U.S. Patent No. 5,423,803 and U.S. Patent No. 6,036,684 are incorporated herein by reference." Thus, the instant specification incorporates the entire *process* of US 6,036,684 and US 5,423,803.

Applicant filed an amendment to the specification on 1/7/08 inserting portions of Tankovich's (US 6,036,684) process. The portions inserted recite, "Laser energy at 1.06 wavelength has an extinction length in human skin of several millimeters but is highly absorbed in the graphite particles below the surface and upon absorption of the energy from the third pulse, the particles explode violently ripping off the dead cells of the stratum corneum which lay above the exploding cells." Further, a portion recites, "The

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skin is fairly effectively shielded from the pulse by the second layer. But the third pulse interacts with the skin and the carbon particles below the skin." "Fairly" shielded clearly indicates that *some* of the skin is removed during the second pulse. Neither the instant specification nor US 6,036,684 ever state that the first and second pulse never remove any skin cells. US 5,423,803 to Tankovich which is also incorporated by reference discloses, "A process for the removal of superficial epidermal skin cells in human skin comprising the steps of: a. topically applying to a section of said skin a contaminant having a high absorption at least one frequency band of light which penetrates the outer layers of human epidermis, b. forcing some of said contaminant to infiltrate into spaces between said superficial epidermal skins cells, and c. illuminating said section of skin with pulses of said at least one frequency band of light, at least one of said pulses having sufficient energy to cause at least a portion of said contaminant to explode so as to tear off some of said superficial epidermal skin cells." Clearly US '803, which is incorporated in its *entirety*, is not only directed to removing skin, US '803 indicate that any of the pulses can remove *some* skin. Additionally, the instant specification on page 6, discloses that retinoic acid attacks the cell glue making the stratum corneum thinner. Applicant's process is directed to applying retinoic acid as a pretreatment. Thus, the stratum corneum is in a weakened condition. Therefore, since the "glue" that adheres the cells together is weakened, the force of the explosion in the first and second pulse will remove at least *some* of the weakened skin cells. The examiner points out that even if a few skin cells are removed, that is enough to render the recitation, "does not remove skin" new matter.

Further, instant claims do not exclude application of third pulse that removes skin, which is contrary to the limitation "leaves epidermis intact". Figure 3 of the instant specification discloses, "Move laser across skin to explode the graphite particles and reveal the underlying skin". Clearly, the underlying skin cannot be revealed unless skin is removed. The instant specification discloses "wounding" the skin and page 6, line 2 discloses, "beginning at the sixth month from the initial wounding, a series of booster laser treatments is given until the desired skin resurfacing end point is reached." The definition of a wound is "An injury, especially one in which the skin or another external surface is torn, pierced, cut, or otherwise broken." Thus, wounding implies removal of *some* skin. Moreover, applicant clearly discloses the process resurfaces the skin. Applicant utilizes a laser and clearly discloses on page 6, line 2 that the skin is resurfaced. Note the attached definitions. Laser *resurfacing* is known to remove skin. <http://www.surgeryencyclopedia.com/La-Pa/Laser-Skin-Resurfacing.html> discloses, "The purpose of laser skin resurfacing is to use the heat generated by extremely focused light to remove the upper to middle layers of the skin." Lastly, examiner notes that skin rejuvenation includes improving scars, acne, skin pigmentation, etc. Again it is noted that applicant incorporates US 5,423,803 in its entirety. US '803 process as discussed above is directed to removing skin. US '803 discloses removing tattoos (reads on improving skin pigmentation) by removing the skin. Thus, applicant does not have support for completely excluding any removal of skin. Again it is reiterated that applicant has incorporated by reference the entire process disclosed by Tankovich, which is directed to using three pulses to achieve the cosmetic benefit.

Claims 21, 23-29, 33-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Enablement is considered in the view of the Wands factors (MPEP 2164.01 (a)). These include the nature of the claims, guidance of the specification, the existence of working examples, predictability of the prior art, and state of the prior art. All of the Wands factors have been considered with the regard to the instant claims, with the most relevant discussed below. The instant claims are not enabled to prevent healing of the skin indefinitely and the process of treatment by prevention of healing.

Nature of the Invention: The rejected claims are drawn to the method of producing sustained skin rejuvenation comprising: a) pre-treating the skin with a retinoic acid; b) exploding a contaminant on the skin using laser light of a wavelength of 800-1200nm, a fluence of 1-3 J/cm³, and a pulse duration of 0.001-1 microsecond; c) applying retinoic acid to the skin 4-16 times after step b, and d) repeating treatment once every twelve months. Skin rejuvenation includes improving acne, wrinkles, scars, skin pigmentation, etc. Instant claims now require epidermis is intact and undamaged and stratum corneum not removed.

Breath of the claims: The breadth of the claim encompasses preventing any skin removal after exploding a contaminant such as graphite or carbon using a laser

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and only using one to two pulses to attain skin rejuvenation which includes acne, wrinkles, scars, skin pigmentation, etc.

Guidance of the Specification: The instant specification incorporates the entire *process* of US 6,036,684 to Tankovich et al and US 5,423,803 to Tankovich et al.

Therefore, Tankovich's disclosure is necessarily present in the instant specification and is part of the guidance of the specification. Both US '684 and US '803 are directed to removing skin to attain cosmetic benefit using at least 3 pulses. US '684 discloses that about 5 pulses are required to treat acne. US '803 discloses that to remove skin pigmentation such as a tattoo, removal of the skin is necessary. Figure 3 of the instant specification discloses the method in which the cosmetic benefit is attained: "Move laser across skin to explode the graphite particles and reveal the underlying skin". Further, the instant specification discloses on page 6, line 2 discloses, "beginning at the sixth month from the initial wounding, a series of booster laser treatments is given until the desired skin resurfacing end point is reached." Therefore, the guidance of the specification is directed to removing at least some skin to attain the cosmetic benefit.

However, applicant's specification does not describe a method using pulses and the parameters of the laser such that the epidermis is undamaged. For instance, it is unclear what the setting of the wave length, the pulse duration, and the fluence is for a one or two pulse treatment and if this setting changes with the type of skin improvement. For instance, the specification does not provide any guidance of the parameters of treating wrinkles versus treating infections, veins, etc. The only guidance

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of the parameters and number of pulses in correlation with the given treatment is from Tankovich.

The State of the Art: <http://www.surgeryencyclopedia.com/La-Pa/Laser-Skin-Resurfacing.html> discloses, "Laser skin resurfacing involves the application of laser light to the skin in order to remove fine wrinkles and tighten the skin surface. The purpose of laser skin resurfacing is to use the heat generated by extremely focused light to remove the upper to middle layers of the skin." Thus, the instant specification discloses using "skin resurfacing" on page 6 to render the cosmetic benefit and the state of the art indicates that "skin resurfacing" is the removal of skin. Therefore, if the skin is not removed, then the skin is not resurfaced and the cosmetic benefit is not attained.

As discussed above, US 6,036,684, to Tankovich, discloses an identical process using the same fluence, pulse duration, and wavelength. Tankovich discloses that about 5 pulses are required to treat acne. Applicant incorporates Tankovich's process by reference. Thus, clearly indicating that one or two pulses will not achieve the cosmetic benefit of treating acne as claimed in dependent claim 36.

The laser art indicates that there is nonablative laser surgery and ablative laser surgery. In ablative laser surgery, a laser works by vaporizing the top layer of the skin to remove blemishes, scars and wrinkles. <http://ivseasonsskincare.com/NAR.html> discloses, "Non-Ablative Skin Rejuvenation is a non-surgical process that gives significant improvement in mild to moderate skin lines by combining gentle light laser treatments with Particle Skin Resurfacing (PSR). The results of Non-Ablative Rejuvenation procedures are much more subtle and gradual than those obtained with

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ablative procedures such as the Carbon Dioxide or Erbium Lasers. Non-Ablative Skin Rejuvenation aims to bypass the injury to the epidermis while stimulating collagen remodeling with dermal heating, as well as significantly improving red vessels and lesions. The instant invention is directed to non-ablative procedures since applicant uses a laser with PSR to stimulate collagen production.

<http://www.plasticsurgeryadvisor.com/skin-resurfacing-surgery/non-ablative-laser-surgery.shtml> discloses in non-ablative laser surgery, the laser removes tissue beneath the first layer of skin (in the epidermis).

Therefore, the prior art indicates that some skin either in the stratum corneum or beneath the stratum corneum will be removed by laser surgery to attain cosmetic benefits.

Working Examples: Figure 4 shows the effect of "laser method of the present invention on the restoration of the skin of a patient suffering from acne vulgaris". It is noted that the specification incorporates Tankovich's laser method by reference. Note page 5. The only contemplation of the number of pulses used to provide skin rejuvenation, let alone improve acne can only be derived from Tankovich's process, which is incorporated by reference. Tankovich discloses the use of about 5 pulses and also some removal of skin.

Predictability of the Art: The lack of significant guidance from the specification or the prior art with regard to exploding a contaminant using lasers such that the treatment prevents the removal of any skin to attain a cosmetic benefit makes practicing the instant invention unpredictable.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

The rejection of claims 21, 23-29, 33-40 under 35 U.S.C. 103(a) as being unpatentable over Goldberg et al (Skin resurfacing utilizing a low-fluence Nd:YAG laser, J Cutan Laser Ther. 1999:1:23-27) in view of Alster (Combined Laser Resurfacing and Tretinoin Treatment of Facial Rhytides, Cosmetic Dermatology, Volume 10, No. 11, November 1997) in view of Ho et al (Dermatologic Surgery. 1995 December, 21(12), 1035-7) and Kye YC (Dermatologic Surgery 1997 October, 23(10): 880-883) is withdrawn in light of applicant's amendment.

However, the rejection will be reinstated once the new matter is removed.

It is to be noted that new claims 39 and 40 also recite not removing stratum corneum. While claim 38 requires skin producing wound in the ret peg area of high dermis, presently all claims are rejected for lack of Written Description and once this rejection is overcome, the claims will be rejected over prior art as appropriate.

Pertinent Prior Art

Goldberg et al (Skin resurfacing utilizing a low-fluence Nd:YAG laser, J Cutan Laser Ther. 1999:1:23-27) is cited as pertinent prior art. Goldberg et al teach nonablative skin resurfacing using 1064-nm Q-switched Nd:YAG laser potentiated by a

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carbon solution at a fluence of 2.5J/cm, repetition rate of 1-10 HZ, and a pulse duration of 6-20ns to treat rhytides (wrinkles).

Conclusion

All the claims are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -5.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila G. Landau can be reached on 571-272-0614. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lakshmi S Channavajjala/
Primary Examiner, Art Unit 1611
June 22, 2009